



DLA Piper LLP (US)
1251 Avenue of the Americas
27th Floor
New York, New York 10020-1104
www.dlapiper.com

Loren H. Brown
loren.brown@us.dlapiper.com
T 212.335.4846
F 212.884.8546

April 14, 2023

VIA ECF

Hon. Katherine Polk Failla
U.S. District Court for the Southern District of New York
Thurgood Marshall U.S. Courthouse
40 Foley Square, Courtroom 618
New York, NY 10007

MEMO ENDORSED

Re: *In re: Chantix (Varenicline) Marketing, Sales Practices and Products Liability Litigation (No. II)*, 22-MD-3050 (KPF), 22-MC-3050 (KPF)

Dear Judge Failla:

We write on behalf of Defendant Pfizer Inc. (“Pfizer”) in response to Temporary Plaintiffs’ Counsel’s April 11, 2023 letter to the Court seeking proposed “core discovery” that Pfizer would produce during the pendency of Pfizer’s forthcoming Motion to Dismiss the Master Complaint (“Motion to Dismiss”) (ECF No. 31).

As Pfizer informed the Court at the initial conference and consistent with the Court’s practice, Pfizer believes all discovery should be stayed until the Court issues its decision on Pfizer’s forthcoming Motion to Dismiss, which it believes will be dispositive. *See SEC v. Farnsworth*, No. 1:22-cv-8226, ECF No. 30 (S.D.N.Y. Oct. 28, 2022) (Failla, J.). “[A] stay may be warranted upon consideration of several factors, including ‘[i] whether a defendant has made a strong showing that the plaintiff’s claim is unmeritorious, [ii] the breadth of discovery and the burden of responding to it, and [iii] the risk of unfair prejudice to the party opposing the stay.’” *Geller Biopharm, Inc. v. Amunix Pharm., Inc.*, No. 1:20-cv-04334, ECF No. 27 (S.D.N.Y. Sept. 9, 2020) (Failla, J.) (internal quotation omitted). As discussed further below, all three factors support staying discovery here, including the substantial undue burden of Temporary Plaintiffs’ Counsel’s purported “core discovery” requests.

First, there is a substantial chance that Pfizer’s forthcoming Motion Dismiss will be dispositive and obviate the need for any discovery. “[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, ‘this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.’” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (internal quotation omitted). Pfizer previously demonstrated that claims based on this factual premise lacked merit and we anticipate



Hon. Katherine Polk Failla

April 14, 2023

Page Two

that the consolidated complaint will be materially similar and legally insufficient regardless of any additional facts or claims pled. Temporary Plaintiffs' Counsel should not now be able to seek discovery in the hope that this discovery will allow them to state a claim.

Second, Temporary Plaintiffs' Counsel's "core discovery" proposal is not what the name implies. Contrary to the targeted list of low-hanging fruit promised, the requests would impose substantial undue burden, effort and costs before the Court adjudicates Pfizer's Motion to Dismiss.¹ Specifically, it would be unduly burdensome for Pfizer to search for, review and produce the *nine* separate categories of discovery² identified as "core discovery" in Temporary Plaintiffs' Counsel's letter. To highlight only some examples of the proposal's expansive nature:

- Plaintiffs seek the Chantix New Drug Application ("NDA") file, the proposal that Pfizer submitted to the Food and Drug Administration to obtain Chantix's approval, and certain communications with regulators, which are voluminous. Pfizer estimates that these files alone will total more than 500,000 pages of documents and could take two months to procure, review, and produce.
- Plaintiffs' request for FDA inspectional documents implicates a significant number of reports for multiple facilities for an undetermined time period. It would take a significant amount of time to parse through these reports and determine which, if any, relate to machinery that are used to manufacture Chantix.

Courts routinely grant motions to stay discovery when the requested discovery sought creates an undue burden. *See, e.g., HABA Glob., Inc. v. Barclays*, 2020 WL 832341, at *1 (S.D.N.Y. Feb. 20, 2020) ("[T]he Court finds that 'proceeding with discovery while the motion is pending would waste the parties' resources and would constitute an undue burden on' Defendants.") (citation to internal quotations omitted); *Geller Biopharm, Inc. v. Amunix Pharm., Inc.*, No. 1:20-cv-04334, ECF No. 27 (S.D.N.Y. Sept. 9, 2020) (Failla, J.) (staying discovery due to plaintiffs' "broad" discovery requests).

¹ Pfizer reserves its right to serve formal objections and responses to these requests, should any discovery be permitted.

² Of course, before Pfizer can produce any discovery, the parties will need to negotiate, and the Court enter, at least two procedural orders: a protective order regarding confidential information and an order governing electronically stored information ("ESI"). A protective order is necessary since most of the requested documents contain information deemed confidential under FDA regulations and/or concern Pfizer's proprietary manufacturing practices. In Pfizer's counsel's experience, it can take several weeks to negotiate and finalize these proposed orders, and there could be disputes the Court would need to resolve. Pfizer already has agreed to work with Temporary Plaintiffs' Counsel on those orders while its Motion to Dismiss is pending, which would serve the purpose of advancing preparation for discovery in the unlikely event that claims were to survive Pfizer's Motion to Dismiss.



Hon. Katherine Polk Failla

April 14, 2023

Page Three

Third, Plaintiffs will not suffer any prejudice as a result of the stay. “[A] temporary and finite delay in attaining discovery” is not prejudicial when “there are no time-sensitive claims at issue.” *In re AOL Time Warner, Inc. Sec. and ERISA Litig.*, 2003 WL 22227945, at *2 (S.D.N.Y. 2003) (granting stay); *see also Rivera v. Heyman*, 1997 WL 86394, at *1 (S.D.N.Y. Feb. 27, 1997) (“A stay pending determination of a dispositive motion that potentially eliminates the entire action will neither substantially nor unduly delay the action, should it continue.”). While Temporary Plaintiffs’ Counsel has argued that resolution of their case has been delayed while the parties litigated the appropriate forum for these cases, those delays were a function of Temporary Plaintiffs’ Counsel’s agreed approach to determining venue and their repeated objections to transferring to this Court.³ In light of that history, Temporary Plaintiffs’ Counsel’s complaints of delay ring hollow.

For these reasons, Pfizer respectfully requests that the Court deny Temporary Plaintiffs’ Counsel’s request for the production of certain “core discovery” at this stage and instead enter a stay of all discovery until the Court issues its decision on Pfizer’s forthcoming Motion to Dismiss.

Respectfully,

/s/ *Loren H. Brown*

Loren H. Brown

cc: Counsel of Record

³ In fact, more than a year ago, a magistrate judge in the Southern District of Florida ordered the case where the parties were litigating venue (which is now in this MDL) be transferred to this District. Rather than accepting transfer, Temporary Plaintiffs’ Counsel repeatedly challenged the original transfer recommendation and then applied for the creation of a multi-district litigation (“MDL”) in the district where *In re Valsartan* is pending.

The Court is in receipt of Plaintiffs' "core discovery" proposal for discovery while Defendant's contemplated motion to dismiss is pending (Dkt. #31), as well as Defendant's above opposition (Dkt. #34). The Court has carefully considered Plaintiffs' proposal, and does not believe that discovery is warranted while the Court considers Defendant's motion to dismiss.

As the parties are aware, it is this Court's general practice to stay discovery while a dispositive motion to dismiss is pending. Defendant intends to file a fully dispositive motion to dismiss the forthcoming Master Complaint, and this Court's resolution of that motion may obviate the need for any discovery or narrow the issues relevant to discovery.

Second, the Court agrees with Defendant that Plaintiffs' proposal still poses substantial burdens on Defendant, despite being somewhat limited in scope. Plaintiffs seek discovery on nine categories of documents related to (i) nitrosamine testing; (ii) communications with regulators; (iii) manufacturing practices; and (iv) inspection and approval of Chantix. (Dkt. #31 at 1-2). Although the Court agrees that some of these requests may be easy to search for and produce, including the NDA file, others will require substantial searching and review for responsiveness and privilege. These include communications with various regulators as well as inspections conducted by those regulators.

Finally, the Court does not believe that staying discovery will pose any meaningful prejudice to Plaintiffs or delay this case. Again, the Court cannot prejudge Defendant's motion at this time, and the motion may obviate the need for discovery or at least narrow its scope. In the event that all of Plaintiffs' requested "core discovery" remains necessary should the Court not grant Defendant's motion, the Court believes that such discovery can be done alongside any other discovery. Although the parties are not in full agreement on a discovery schedule following motion to dismiss practice (Dkt. #25), both sides have proposed a lengthy discovery schedule which would subsume all of Plaintiff's requested "core discovery."

As such, the Court DENIES Plaintiffs' core discovery proposal and will stay discovery while it considers briefing on the contemplated motion to dismiss.

Dated: April 17, 2023
New York, New York

SO ORDERED.

A handwritten signature in blue ink, reading "Katherine Polk Failla".

HON. KATHERINE POLK FAILLA
UNITED STATES DISTRICT JUDGE